

FORM PTO-1390 (REV 10-94)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				01-407
INTERNATIONAL APPLICATION NO. PCT/EP99/10399		INTERNATIONAL FILING DATE December 28, 1999		U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.55) <b>09/890715</b>
TITLE OF INVENTION METHOD FOR SEVERING OR REMOVING A BIOLOGICAL STRUCTURE, ESPECIALLY BONES		PRIORITY DATE CLAIMED February 5, 1999		
APPLICANT(S) FOR DO/EO/US Michael Butsch et al.				
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:				
<ol style="list-style-type: none"> <li><input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</li> <li><input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</li> <li><input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</li> <li><input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</li> <li><input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li><input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li><input checked="" type="checkbox"/> has been transmitted by the International Bureau.</li> <li><input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li><input checked="" type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</li> <li><input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li><input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li><input type="checkbox"/> have been transmitted by the International Bureau.</li> <li><input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li><input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li><input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li><input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li><input checked="" type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>				
Items 11. to 16. below concern document(s) or information included:				
<ol style="list-style-type: none"> <li><input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li><input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li><input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</li> <li><input type="checkbox"/> A substitute specification.</li> <li><input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li><input checked="" type="checkbox"/> Other items or information: Applicant claims small entity status.</li> </ol>				

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(January 1995)

on August 3, 2001  
(Date of Deposit)  
Rachel Piscitelli  
(Name and Reg. No. of Attorney)  
Rachel Piscitelli  
(Signature)  
August 3, 2001  
(Date of Signature)

JC17 Rec'd PCT/PTO 03 AUG 2001

U.S. APPLICATION NO. <b>09/890715</b> INTERNATIONAL APPLICATION NO. <b>PCT/EP99/10399</b>		ATTORNEY'S DOCKET NUMBER <b>01-407</b>	
17. <input checked="" type="checkbox"/> The following fees are submitted: <b>BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):</b> Search Report has been prepared by the EPO or JPO..... \$860.00  International preliminary examination fee paid to USPTO (37 CFR 1.482) ..... No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))..  Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO..... \$1,000.00  International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....  <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>		<b>CALCULATIONS</b> <b>PTO USE ONLY</b>	
<b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>		\$	860.00
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$	130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	17      -20 =		X \$18
Independent claims	3      -3 =		X \$80
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270
<b>TOTAL OF ABOVE CALCULATIONS =</b>			\$ 990.00
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).			\$ 495.00
<b>SUBTOTAL =</b>			\$ 495.00
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			\$
<b>TOTAL NATIONAL FEE =</b>			\$ 495.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property			\$
<b>TOTAL FEES ENCLOSED =</b>			\$ 495.00
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a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>495.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>02-0184</u> . A duplicate copy of this sheet is enclosed.			
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.			
SEND ALL CORRESPONDENCE TO:  <b>GREGORY P. LAPOINTE</b> <b>BACHMAN &amp; LAPOINTE, P.C.</b> <b>900 CHAPEL ST., SUITE 1201</b> <b>NEW HAVEN, CT 06510-2802</b>		<div style="text-align: center;">             SIGNATURE  <b>Gregory P. LaPointe</b>            NAME  <b>28,395</b>            REGISTRATION NUMBER         </div>	

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August 3, 2002  
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09/890715

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Michael Butsch et al.                      Docket No.: 01-407  
Serial No.:    Examiner :  
Filed :    Art Unit :  
PCT No. : PCT/EP99/10399  
IFD : December 28, 1999  
For : METHOD FOR SEVERING OR REMOVING A BIOLOGICAL  
STRUCTURE, ESPECIALLY BONES

Suite 1201  
900 Chapel Street  
New Haven, CT 06510-2802

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents & Trademarks  
United States Patent & Trademark Office  
Washington, D.C. 20231

Dear Sir:

In the above-identified application for United States patent,  
please amend as follows.

IN THE CLAIMS

Cancel claims 1-8 and amend claims 11-13, 17 and 19-23 as  
follows.

11. (Amended) The water-jet cutting system as claimed in claim 9, characterized in that the pressure-generating device (1) has a linear drive (7), in particular an electromechanically operated linear actuator, which applies pressure to a plunger element (6) of the supply reservoir (2).

12. (Amended) The water-jet cutting system as claimed in claim 9, characterized in that the supply reservoir (2), via at least one quick-acting lock (8), if necessary as a thread or as a bayonet lock, is connected to the pressure-generating device (1) in such a way that it can be released again.

13. (Amended) The water-jet cutting system as claimed in claim 9, characterized in that at least two pressure-generating devices (1) having interchangeable supply reservoirs (2) can be connected to one cutting-nozzle element (S, S<sub>1</sub> to S<sub>3</sub>), either the one or the other pressure-generating device (1) delivering the severing medium (4) to the cutting-nozzle element (S, S<sub>1</sub> to S<sub>3</sub>).

17. (Amended) The cutting-nozzle element as claimed in claim 15, characterized in that the shut-off element (14) is arranged inside the nozzle body (12) in such a way that it can be moved in a translatory and/or rotational manner, in particular in a reciprocating manner.

19. (Amended) The cutting-nozzle element as claimed in claim 15, characterized in that a gap or conical annular gap

(16), through which the severing medium (4) flows, is formed in between cutting-nozzle body (12) and shut-off element (14).

20. (Amended) The cutting-nozzle element as claimed in claim 15, characterized in that, to draw off severing medium and biological substances, the shut-off element (14) is designed like a hollow shaft and projects at the end face from the cutting-nozzle body (12).

21. (Amended) The cutting-nozzle element as claimed in claim 15, characterized in that the shut-off element (14) is provided with a shaft shoulder (18) which closes the nozzle opening (13) and to which pressure is applied axially by means of an energy-storing element (19).

22. (Amended) The cutting-nozzle element as claimed in claim 15, characterized in that an elastic tube element (22) adjoins the shut-off element (14) for drawing off and compensates for a translatory and/or rotational movement of the shut-off element (14).

23. (Amended) The cutting-nozzle element as claimed in claim 15, characterized in that a rotatable shut-off element (14) is inserted into the cutting-nozzle body (12).

REMARKS

Claims 1-8 are cancelled and claims 11-13, 17 and 19-23 have been amended in order to delete the multiple dependencies in order to conform with U.S. practice. An early action on the merits is respectfully requested.

If any fees are required in connection with this case, it is respectfully requested that they be charged to Deposit Account No. 02-0184.

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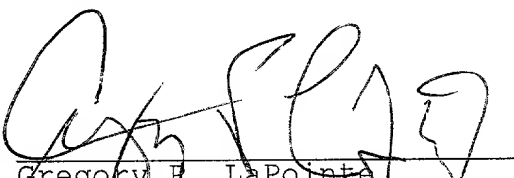
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Name and Reg. No. of Attorney  
Rachel Piscitelli  
Signature  
August 3, 2001  
(Date of Signature)

Date: August 3, 2001

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Respectfully submitted,

Michael Butsch et al.

By   
Gregory F. LaPointe  
Attorney for Applicant  
Telephone - (203) 777-6628

Version with markings to show changes made to claims

11. (Amended) The water-jet cutting system as claimed in claim 9 [or 10], characterized in that the pressure-generating device (1) has a linear drive (7), in particular an electromechanically operated linear actuator, which applies pressure to a plunger element (6) of the supply reservoir (2).

12. (Amended) The water-jet cutting system as claimed in [at least one of claims 9 to 11] claim 9, characterized in that the supply reservoir (2), via at least one quick-acting lock (8), if necessary as a thread or as a bayonet lock, is connected to the pressure-generating device (1) in such a way that it can be released again.

13. (Amended) The water-jet cutting system as claimed in [at least one of claims 9 to 12] claim 9, characterized in that at least two pressure-generating devices (1) having interchangeable supply reservoirs (2) can be connected to one cutting-nozzle element (S, S<sub>1</sub> to S<sub>3</sub>), either the one or the other pressure-generating device (1) delivering the severing medium (4) to the cutting-nozzle element (S, S<sub>1</sub> to S<sub>3</sub>).

17. (Amended) The cutting-nozzle element as claimed in claim 15 [or 16], characterized in that the shut-off element (14) is arranged inside the nozzle body (12) in such a way that it can be moved in a translatory and/or rotational manner, in particular in a reciprocating manner.

19. (Amended) The cutting-nozzle element as claimed in [at least one of claims 15 to 18] claim 15, characterized in that a gap or conical annular gap (16), through which the severing medium (4) flows, is formed in between cutting-nozzle body (12) and shut-off element (14).

20. (Amended) The cutting-nozzle element as claimed in [at least one of claims 15 to 19] claim 15, characterized in that, to draw off severing medium and biological substances, the shut-off element (14) is designed like a hollow shaft and projects at the end face from the cutting-nozzle body (12).

21. (Amended) The cutting-nozzle element as claimed in [at least one of claims 15 to 20] claim 15, characterized in that the shut-off element (14) is provided with a shaft shoulder (18) which closes the nozzle opening (13) and to which pressure is applied axially by means of an energy-storing element (19).



22. (Amended) The cutting-nozzle element as claimed in [at least one of claims 15 to 21] claim 15, characterized in that an elastic tube element (22) adjoins the shut-off element (14) for drawing off and compensates for a translatory and/or rotational movement of the shut-off element (14).

23. (Amended) The cutting-nozzle element as claimed in [at least one of claims 15 to 22] claim 15, characterized in that a rotatable shut-off element (14) is inserted into the cutting-nozzle body (12).

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

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4/PRTS

Method of severing or removing abiological structure, in particular bone

The invention relates to a method of severing or removing a biological structure, in particular bone, having a water-jet cutting system from which a severing medium under high pressure is discharged, and to a cutting-nozzle element and a water-jet cutting system.

Such methods are known on the market and are in use in many different forms and designs. In particular in medicine, it is known to sever, for example from outside, a bone by water-jet cutting. A disadvantage with this is that, in conventional water-jet cutting methods, the soft tissue, and not only the bone, is destroyed. The vascular system in the soft tissue at the bone is important in particular for the knitting of the bone or for the regeneration of the callus. It is therefore necessary during the water-jet removal or severing of biological substances, in particular of bones, to carry out the removal or severing of the bone as carefully as possible. In conventional water-jet cutting methods, the water is applied directly to the exposed bone via a cutting nozzle, in the course of which the vascular system in the bone is also damaged.

An arrangement for cutting by means of a liquid jet has been disclosed by EP 0 636 345 A1, in which arrangement an

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additional medium is added to a liquid jet by means of vacuum. In this case, pulsing of a liquid jet is produced in a handle, the liquid jet being discharged under pressure losses via an elongated cannula adjoining the handle.

The object of the present invention is to provide a method and a water-jet cutting system having a cutting-nozzle element with which removal and/or severing of biological substances, in particular of bones, is possible in a simple and careful manner. The ease of manipulation of corresponding water-jet cutting systems having cutting-nozzle

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REPLACEMENT PAGE

element with which removal and/or severing of biological substances, in particular of bones, is possible in a simple and careful manner. The ease of manipulation of corresponding water-jet cutting systems having cutting-nozzle elements is also to be considerably improved. Furthermore, it is the object of the present invention to shorten the operation times, in particular during the severing of bones, in which case high operation costs are to be reduced as a result. In addition, an operation is to be carried out with substantially greater care and with a quicker recovery for the patient.

This object is achieved by the severing medium being discharged onto the biological structure in a pulsed manner.

This ensures that, in particular, the soft tissue is moved back by a pulsed jet and then the severing medium strikes the bone in order to partly remove the bone or to sever it. In this case, it may be advantageous to insert a corresponding cutting nozzle for severing the bone into the marrow cavity of the bone and to provide the bone radially with a notch from inside. For example, a radially arranged nozzle in a cutting-nozzle element is rotated in the marrow cavity of a tubular bone during the discharge of the severing medium. In the process, the bone can be severed at least partly from inside. It may possibly also be sufficient to cut only one notch in the bone, so that it can subsequently be severed or pierced in a conventional manner from outside by a

small blow. The outer periosteum is not destroyed in the process. Subsequent further treatment of the bone, for example traction, may then be carried out.

However, it is important that a pulsed water jet is discharged from a nozzle opening of a cutting-nozzle body in a quite specific manner via this method, i.e. at a quite specific frequency and with a pressure change. This pulsation or pulsing is defined as a pressure change of a water jet which undergoes either only a slight pressure change or a complete pressure change up to the absolute pressure drop. A biologically suitable inorganic and/or organic abrasive agent can be fed to the severing medium so that the material-removal capacity is considerably increased during the water-jet cutting. In this way, bones can be severed with substantially lower pressures.

However, it is important that the pulsed discharge of the severing medium results in soft, elastic tissue being moved back upon impingement of the severing medium, whereas the bone tissue is severed or removed when the severing medium impinges on said bone tissue.

Owing to the fact that the severing medium is discharged onto the biological structure in a pulsed manner, and working pressures which would lead to destruction of the softer structures without pulsation are used, and these soft biological structures, on account of their higher elasticity

compared with the surrounding harder biological structures, are subjected to lower mechanical loading within the elastic range through suitable selection of the pulsation, the harder biological structures are severed due to the fact that the elasticity or fracture limit is exceeded.

If a cutting-nozzle element is inserted into the bone, a corresponding element, in particular a tube element or the like, is provided in order to draw the discharging medium out of the interior of the bone.

The pulsation is produced in the cutting nozzle essentially by varying cross sections in the cutting-nozzle element itself. This has the advantage that no inertia losses, for example due to long, possibly elastic or resilient, tube lines, would weaken a changing pressure impulse.

So that a corresponding pulsation can be produced in the individual cutting-nozzle elements, a shut-off element sits inside a cutting-nozzle body, this shut-off element influencing a medium, flowing along inside or outside the latter, by a rotational or translatory reciprocating movement. A change of cross section is effected in the process, a pressure change, in particular a pressure drop, is effected. The pressure drop may even approach zero.

However, within the scope of the present invention, it is also intended that the pressure changes can take place

within small and also large ranges. There are no limits to the invention in this respect either.

In the preferred exemplary embodiment, a cutting-nozzle element which has at least one radial cutting-nozzle opening is formed. This cutting-nozzle element is inserted into a bone, if necessary held in a certain position via end spacers (not shown). By axial rotation of the cutting-nozzle body, with simultaneous discharge, a notch is produced in the bone, or the bone is even severed. So that the outflowing severing medium does not remain in the bone interior space, the corresponding shut-off element, which is provided inside the cutting-nozzle body, is designed as a hollow shaft and can draw the liquid out of the interior space of the bone. So that other uses for severing or removing bones are also possible, cutting-nozzle elements which have end nozzle openings are shown in other exemplary embodiments. These nozzle openings can also be opened and closed at a certain frequency, which is selectable, so that a pulsed water jet can be discharged.

A corresponding water-jet cutting system is equipped with an interchangeable supply reservoir of varying size, in which case the supply reservoir can essentially be connected to a pressure-generating device in an interchangeable manner. The pressure-generating device is preferably of electromechanical type and moves a linear drive onto a

plunger element. As a result, a pressure which can be supplied to the cutting-nozzle element via a connecting line is generated in a pressure space. The supply reservoirs are preferably of a size which can be selected so as to vary and contain the severing medium with, if necessary, abrasive agents.

Only the cutting-nozzle element has to be cleaned after the operation. The supply reservoir is merely exchanged and can be recycled after use.

Furthermore, it is advantageous that such a water-jet cutting system is exceptionally small and can be produced cost-effectively, since any desired supply reservoir can be mounted on the pressure-generating device.

Further advantages, features and details of the invention follow from the description below of preferred exemplary embodiments and with reference to the drawing, in which:

Figure 1 shows a schematic plan view of a water-jet cutting system according to the invention with interchangeable supply reservoir;

Figure 2 shows a schematic partial longitudinal section through a cutting-nozzle element according to the invention;

Figure 3 shows a partial longitudinal section through a further exemplary embodiment of a further cutting-nozzle element;



Figure 4 shows a schematic partial longitudinal section through a further exemplary embodiment of the cutting-nozzle element.

According to figure 1, a water-jet cutting system R according to the invention for severing or removing a biological structure, in particular a human bone, has a pressure-generating device 1, adjoining which, preferably in an interchangeable manner, is a supply reservoir 2. The supply reservoir 2 has a pressure space 3 in which a severing medium 4 is introduced. The severing medium 4 is preferably sterile and aseptic water, which, if necessary, is enriched with abrasive agent 5. The abrasive agents 5 used may be inorganic or organic substances, such as, for example, sodium chloride, biological amino acids, monosaccharides and disaccharides and also sugars and alcohols. These abrasive agents 5 may also be supplied via injectors or the like (not shown here).

The supply reservoir 2 is closed by means of a plunger element 6, which can be actuated via a linear drive 7 of the pressure-generating device 1. The linear drive 7 is preferably an extendable mechanical spindle which can be driven in particular as an electromechanically operated linear actuator of the pressure-generating device 1. Via gearing and things such as drive elements (not shown here), the spindle can be extended and can exert a very high

pressure on the plunger 6. In this case, the supply reservoir 2 is supported on the pressure-generating device 1 via a quick-acting lock 8. The quick-acting lock 8 may be of the most varied type and have a threaded connection, a push-in connection, a bayonet lock or the like. There are no limits to the invention in this respect.

However, it is important that, after the severing medium 4 has been completely discharged from the pressure space 3 by moving the plunger element 6 in the direction of an outlet valve 9, the medium 4 is fed completely to the cutting-nozzle element S via a connecting line 10. The severing medium 4 is discharged there radially or axially under very high pressure.

The outlet valve 9 is preferably designed as a check valve. This check valve is connected to the connecting line 10 such that it can be released again, in which case consideration may also be given to producing a releasable connection between outlet valve 9 and pressure-generating device 1.

The functioning of the present water-jet cutting system is as follows:

For the water-jet cutting, a severing medium under pressure, in particular in a pressurized manner is fed to the cutting-nozzle element S. To this end, the supply reservoir 2 is mounted on the pressure-generating device 1. The severing

medium 4 is poured in. The supply reservoir 2 is then pressurized by being acted upon by the plunger 6 via the linear drive 7, so that the severing medium 4 can be fed completely to the cutting-nozzle element S via the connecting line 10. So that there is no idle time during the operation, when a supply reservoir is empty for example, a second pressure-generating device 1 having a second supply reservoir 2 may be provided, this second pressure-generating device 1 jointly feeding the severing medium 4 to the cutting-nozzle element S via a directional control valve 11. While the one supply reservoir is being emptied during the operation, the other supply reservoir can be exchanged.

From the present inventive idea, different supply reservoirs 2 which have capacities of different size for severing agents and which fit, for example, onto a single pressure-generating device 1 are also to be designed.

Shown in figure 2 is a possible cutting-nozzle element S<sub>1</sub> which has a cutting-nozzle body 12 which is designed to be hollow in the interior. In the preferred exemplary embodiment, at least one nozzle opening 13 is provided radially, through which the severing medium 4 flows out under very high pressure for the severing, cutting or removal.

Provided inside the cutting-nozzle body 13 is a shut-off element 14 which is axially movable in a reciprocating manner, as shown in double arrow direction Y.

The shut-off element 14 forms a cone-like annular gap 16 via a cone 15 of the cutting-nozzle body 12, this cone 15 having a corresponding profile of the same kind.

Following the cone 15, the shut-off element 14 is of constricted design and forms an annular space 17 relative to the cutting-nozzle body 14, the severing medium 4 flowing outward out of this annular space 17 through the radial nozzle openings 13. A shaft shoulder 18 of the shut-off element 14 adjoins the annular space 17 and is connected to the cutting-nozzle body 12 on the inside virtually free of play. Adjoining the shaft shoulder 18, which also serves to center and axially guide the shut-off element 16, is an energy-storing element 19, which is supported at the end face on the shaft shoulder 18 and is supported on the other side at the end face on the cutting-nozzle body 12 on the inside. As a result, the shut-off element 14 is permanently deflected in an X-direction. The severing medium 4 flows through the annular gap 16 and is then discharged from the nozzle openings 13 under high pressure via the annular space 17.

However, it is important in the case of the present invention that a pulsating jet is produced from the nozzle openings 13 on account of a very small annular gap 16 in the region of the cone 15, the severing medium being greatly accelerated in this annular gap 16. This produces a vacuum which further reduces the annular gap 16 until severing

medium 4 no longer flows. As a result, the shut-off element 14 is moved against the X-direction shown. The energy-storing element 19 is thereby loaded and applies pressure to the shut-off element 14. The latter yields to the pressure of the energy-storing element 19 and causes the shut-off element 14 to move in the X-direction shown, so that the severing medium 4 can again flow out through the widened annular gap 16, the adjoining annular space 17 and thus through the nozzle opening 13. This action repeats itself.

A pulsation can be controlled or set on the basis of pressures which can be set in a varying manner and on the basis of selectable energy-storing elements 19 and different geometries of the annular gap 16. This pulsation serves essentially to sever bones and tissue parts. It has proved to be especially favorable to use the pulsation. Tissue structures which must not be damaged, such as the periosteum for example, are moved only within the elastic range by a pulsating jet. The pulsed jet then removes or severs the biological structure, in particular the bone. This ensures that periosteum or other soft tissue is attacked or damaged only slightly during the severing of bone.

A tube element 22, which is preferably of elastic type, adjoins the shut-off element 14. It permits an axial movement of the shut-off element 14 in the Y-direction shown. At the same time, it serves to draw off severing medium 4 which is

located in the bone interior when the cutting-nozzle element  $S_1$  is inserted into a bone interior space.

Shown in a further exemplary embodiment of the present invention according to figure 3 is a cutting-nozzle element  $S_2$  in which the nozzle opening 13 is provided axially at the end face in the cutting-nozzle body 12. A shut-off element 14 is inserted as hollow shaft inside the cutting-nozzle body 12 of hollow design and is rotatable about an axis 20 in the Z-direction shown. A discharge opening 21 is provided at the end face in the shut-off element 14 of hollow design, which fits precisely into the cutting-nozzle body 12, the discharge opening 21 coinciding with the nozzle opening 13 in a certain position. However, the provision of a multiplicity of discharge openings 21 at the end face is also intended to be within the scope of the present invention, so that, when the shut-off element 14 is rotated, the severing medium 4, which is introduced inside the shut-off element 14 under high pressure, discharges outward in a pulsating manner via the discharge opening 21 and when the latter coincides with the nozzle opening 13. The pulsation or the cyclical discharge of severing medium 4 from the nozzle opening 13 can be influenced by the number of corresponding discharge openings 21 or by the rotational speed of the shut-off element 14 about an axis 20. The rotation may be effected in any desired manner, mechanically, electromechanically or some other way.

Shown in the last exemplary embodiment of the present invention according to figure 4 is a cutting-nozzle element  $S_3$  in which the cutting-nozzle body 12 is designed to be hollow and has a nozzle opening 13 at the end face in the region of an axis 20.

The shut-off element 14 sits in an axially movable manner inside the cutting-nozzle body 12 and is of conical design and engages in a correspondingly formed cone of the cutting-nozzle body 12. The severing medium 4 flows between shut-off element 14 and the interior space of the cutting-nozzle body 12 when the annular gap 16 is open. The annular gap 16 is opened and closed by a translatory axial movement of the shut-off element 14 in double arrow direction Y shown. This movement may be produced, for example, mechanically, electromechanically or even by a piezoelectric element. Many different possibilities which are intended to fall within the scope of the invention are conceivable here.

### Patent claims

1. A method of severing or removing a biological structure, in particular bone, having a water-jet cutting system (R) from which a severing medium (4) under high pressure is discharged, characterized in that the severing medium (4) is discharged onto the biological structure in a pulsed manner.
2. A method of severing or removing a biological structure, in particular bone, having a water-jet cutting system (R) from which a severing medium (4) under high pressure is discharged, characterized in that a periosteum is acted upon at least partly from inside by the severing medium (4).
3. The method as claimed in claim 2, characterized in that the periosteum is acted upon by a pulsating severing medium.
4. The method as claimed in at least one of claims 1 to 3, characterized in that an organic and/or inorganic abrasive agent (5) is added to the severing medium (4).
5. The method as claimed in at least one of claims 1 to 4, characterized in that the pulsation of the severing medium (4) is produced directly before discharge in a cutting-nozzle element (S, S<sub>1</sub> to S<sub>4</sub>).
6. The method as claimed in at least one of claims 1 to 5, characterized in that the pulsation is produced by a



pulsating, possibly alternating, pressure change of the severing medium (4) to be discharged.

7. The method as claimed in at least one of claims 1 to 6, characterized in that the pulsation in the cutting-nozzle element (S, S<sub>1</sub> to S<sub>4</sub>) is produced mechanically, pneumatically, electromagnetically according to the piezoelectric effect, or electromagnetically, any desired frequency of the pressure change being set.

8. The method as claimed in at least one of claims 1 to 7, characterized in that the pulsation is produced by utilizing the effect of the increase in the flow velocity of the severing medium in a gap or annular gap (16) while at the same time reducing the pressure and reducing the size of the gap by means of a movable shut-off part (14) which is moved by the vacuum and an energy-storing element which opens the gap again at zero gap and at zero flow.

9. A water-jet cutting system for severing or removing a biological structure, in particular bone, having a pressure-generating device (1) to which at least one cutting-nozzle element (S, S<sub>1</sub> to S<sub>4</sub>) can be connected, characterized in that a supply reservoir (2) having at least one introduced severing medium (4) is assigned to the pressure-generating device (1) in an interchangeable manner.

10. The water-jet cutting system as claimed in claim 9, characterized in that at least one cutting-nozzle element (S,

S<sub>1</sub> to S<sub>4</sub>) can be connected to the supply reservoir (2), in particular to a pressure space (3).

11. The water-jet cutting system as claimed in claim 9 or 10, characterized in that the pressure-generating device (1) has a linear drive (7), in particular an electromechanically operated linear actuator, which applies pressure to a plunger element (6) of the supply reservoir (2).

12. The water-jet cutting system as claimed in at least one of claims 9 to 11, characterized in that the supply reservoir (2), via at least one quick-acting lock (8), if necessary as a thread or as a bayonet lock, is connected to the pressure-generating device (1) in such a way that it can be released again.

13. The water-jet cutting system as claimed in at least one of claims 9 to 12, characterized in that at least two pressure-generating devices (1) having interchangeable supply reservoirs (2) can be connected to one cutting-nozzle element (S, S<sub>1</sub> to S<sub>3</sub>), either the one or the other pressure-generating device (1) delivering the severing medium (4) to the cutting-nozzle element (S, S<sub>1</sub> to S<sub>3</sub>).

14. A cutting-nozzle element for severing or removing a biological structure, in particular bone, to which a severing medium (4) under pressure can be fed, characterized in that at least one nozzle opening (13) is provided at the end face or radially in a cutting-nozzle body (12).

15. The cutting-nozzle element as claimed in claim 14, characterized in that at least one shut-off element (14) for the pulsed closure of the nozzle opening (13) is assigned to the cutting-nozzle body (12).

16. The cutting-nozzle element as claimed in claim 15, characterized in that the shut-off element (14) is arranged inside the nozzle body (12).

17. The cutting-nozzle element as claimed in claim 15 or 16, characterized in that the shut-off element (14) is arranged inside the nozzle body (12) in such a way that it can be moved in a translatory and/or rotational manner, in particular in a reciprocating manner.

18. The cutting-nozzle element as claimed in claim 17, characterized in that the nozzle opening (13) can be closed at intervals in a pulsed manner by the translatory and/or rotational movement of the shut-off element (14).

19. The cutting-nozzle element as claimed in at least one of claims 15 to 18, characterized in that a gap or conical annular gap (16), through which the severing medium (4) flows, is formed in between cutting-nozzle body (12) and shut-off element (14).

20. The cutting-nozzle element as claimed in at least one of claims 15 to 19, characterized in that, to draw off severing medium and biological substances, the shut-off element (14)

is designed like a hollow shaft and projects at the end face from the cutting-nozzle body (12).

21. The cutting-nozzle element as claimed in at least one of claims 15 to 20, characterized in that the shut-off element (14) is provided with a shaft shoulder (18) which closes the nozzle opening (13) and to which pressure is applied axially by means of an energy-storing element (19).

22. The cutting-nozzle element as claimed in at least one of claims 15 to 21, characterized in that an elastic tube element (22) adjoins the shut-off element (14) for drawing off and compensates for a translatory and/or rotational movement of the shut-off element (14).

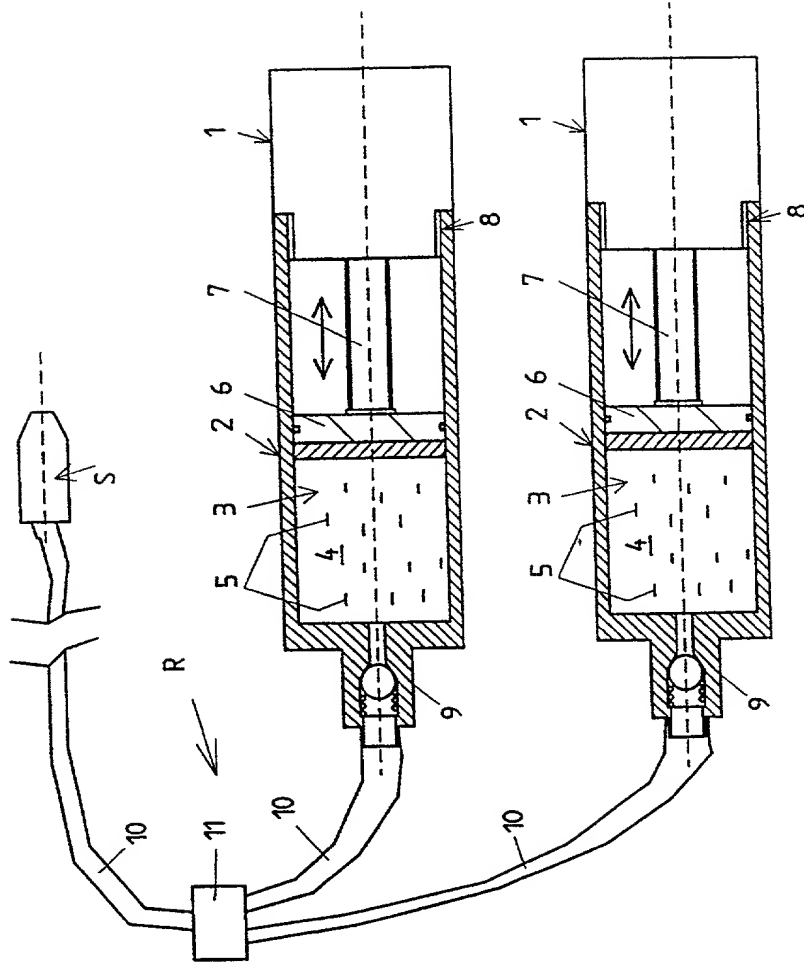
23. The cutting-nozzle element as claimed in at least one of claims 15 to 22, characterized in that a rotatable shut-off element (14) is inserted into the cutting-nozzle body (12).

24. The cutting-nozzle element as claimed in claim 23, characterized in that a severing medium (4) is fed to the shut-off element (14), which has at least one radial or axial discharge opening (13), which can be moved by rotation and/or translation to a coinciding nozzle opening (13) of the cutting-nozzle body (12).

25. The use of components of the common-rail injection technology, in particular for pressure generation, valve technology and electronic control for a water-jet cutting system and/or a cutting-nozzle element.

FIG. 1

Fig. 1



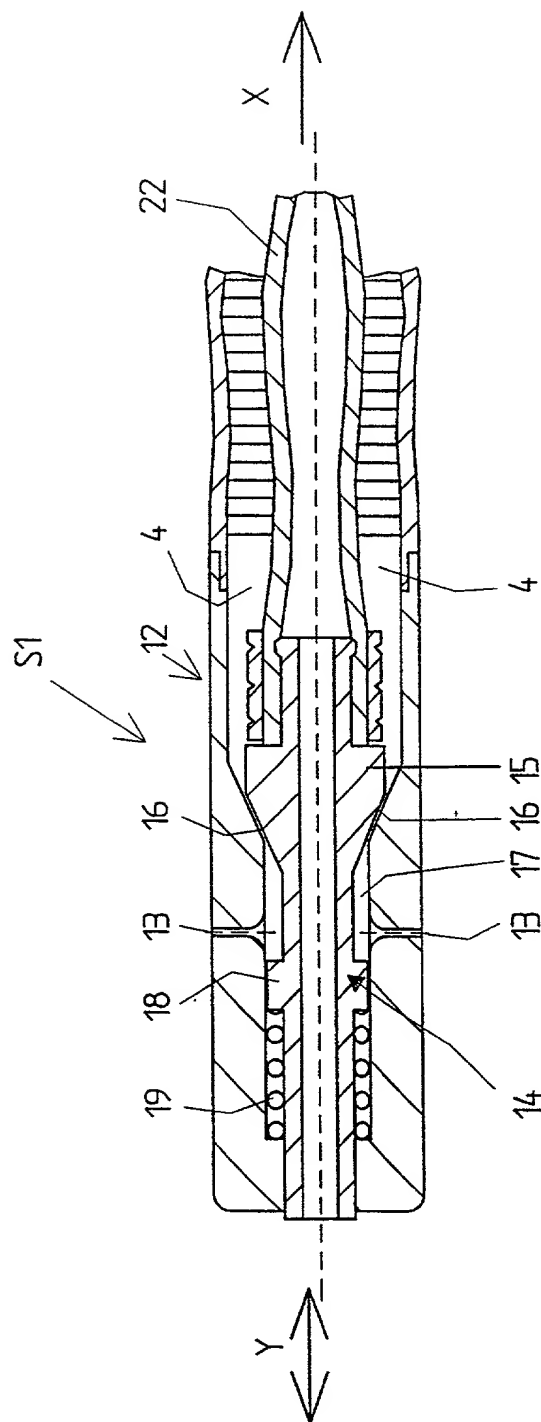


Fig. 2

FIG. 2

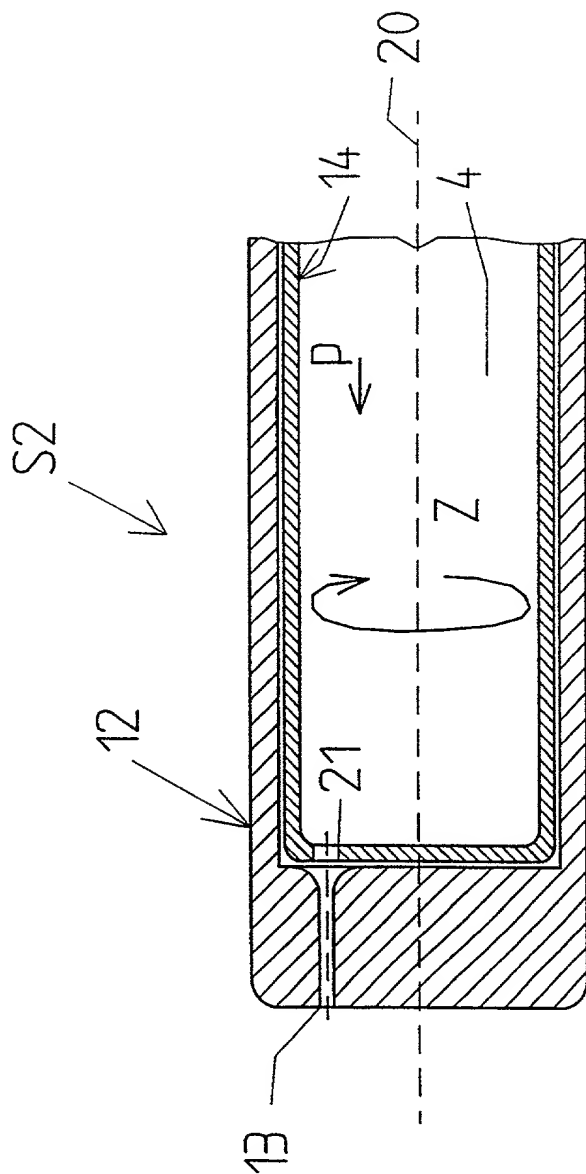


Fig. 3

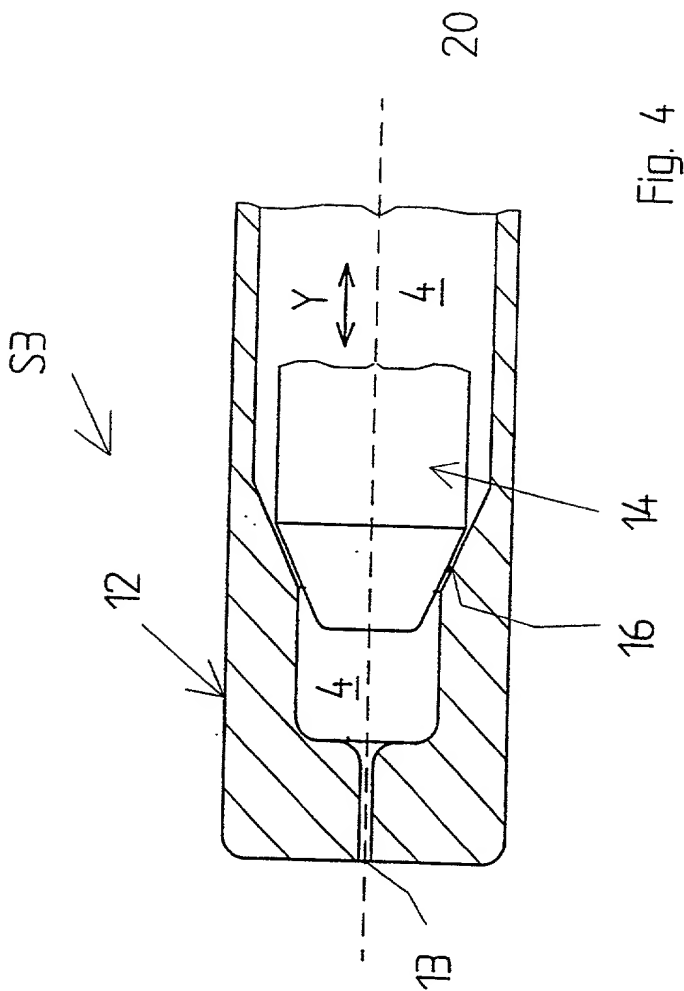


Fig. 4



Practitioner's Docket No. 01-407

PATENT

## COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

## TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

☐ original.☐ design.

NOTE: With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. § 714.16, 7th Edition.

☐ supplemental.

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

☒ national stage of PCT.

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

NOTE: See 37 C.F.R. § 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.

☐ divisional.☐ continuation.

NOTE: Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. § 1.53(b) (application filing requirements — nonprovisional application).

☐ continuation-in-part (C-I-P).

## INVENTORSHIP IDENTIFICATION

**WARNING:** If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

## TITLE OF INVENTION

METHOD FOR SEVERING OR REMOVING A BIOLOGICAL STRUCTURE, ESPECIALLY BONES

(Declaration and Power of Attorney [1-1]—page 1 of 7)

## SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b), or (c))

(a) ☐ is attached hereto.

NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed;  
or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) ☐ was filed on \_\_\_\_\_, as ☐ Serial No. 0 / \_\_\_\_\_  
or ☐ \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. § 1.67.

NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);

"(B) serial number and filing date;

"(C) attorney docket number which was on the specification as filed;

"(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

"(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."

M.P.E.P. § 601.01(a), 7th Ed.

(c) ☒ was described and claimed in PCT International Application No. PCT/EP99/10399, filed on December 28, 1999 and as amended under PCT Article 19 on \_\_\_\_\_ (if any).

(Declaration and Power of Attorney [1-1]—page 2 of 7)

**SUPPLEMENTAL DECLARATION (37 C.F.R. § 1.67(b))**

(complete the following where a supplemental declaration is being submitted)

☐ I hereby declare that the subject matter of the

☐ attached amendment

☐ amendment filed on \_\_\_\_\_

was part of my/our invention and was invented before the filing date of the original application, above-identified, for such invention.

**ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

(also check the following items, if desired)

☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

**PRIORITY CLAIM (35 U.S.C. §§ 119(a)-(d))**

NOTE: "The claim to priority need be in no special form and may be made by the attorney or agent if the foreign application is referred to in the oath or declaration as required by § 1.63. The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) must be filed in the case of an interference (§ 1.630), when necessary to overcome the date of a reference relied upon by the examiner, when specifically required by the examiner, and in all other situations, before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by a petition requesting entry and by the fee set forth in § 1.17(i). If the certified copy is not in the English language, a translation need not be filed except in the case of interference; or when necessary to overcome the date of a reference relied upon by the examiner; or when specifically required by the examiner, in which event an English language translation must be filed together with a statement that the translation of the certified copy is accurate." 37 C.F.R. § 1.55(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §§ 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ☐ no such applications have been filed.

(e) ☒ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION  
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)**

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
Germany	199 04 640.9	5 Feb 1999	<input checked="" type="checkbox"/> YES    NO <input type="checkbox"/>
			<input type="checkbox"/> YES    NO <input type="checkbox"/>
			<input type="checkbox"/> YES    NO <input type="checkbox"/>
			<input type="checkbox"/> YES    NO <input type="checkbox"/>
			<input type="checkbox"/> YES    NO <input type="checkbox"/>

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)**  
(34 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER

FILING DATE

\_\_\_\_ / \_\_\_\_\_  
\_\_\_\_ / \_\_\_\_\_  
\_\_\_\_ / \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S)  
UNDER 35 U.S.C. § 120**

- ☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

(Declaration and Power of Attorney [1-1]—page 4 of 7)

**ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

**POWER OF ATTORNEY**

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

4 Robert H. Bachman (19,374), Gregory P. LaPointe (28,395),  
Barry L. Kelmacher (29,999), and George A. Coury (34,309),  
all of Bachman & LaPointe, P.C., 900 Chapel Street, Suite  
1201, New Haven, CT 06510-2802

(check the following item, if applicable)

- ☒ I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- ☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

**SEND CORRESPONDENCE TO**

☒ Address

Bachman & LaPointe, P.C.  
900 Chapel Street, Suite 1201  
New Haven, CT 06510-2802

☐ Customer Number \_\_\_\_\_

**DIRECT TELEPHONE CALLS TO:**  
(Name and telephone number)

Gregory P. LaPointe  
(203) 777-6628, ext. 111

# DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

NOTE: Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 CFR § 1.63(a)(3).

NOTE: Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997.

Full name of sole or first inventor

Michael Butsch  
(GIVEN NAME) (MIDDLE INITIAL OR NAME) (FAMILY (OR LAST NAME))

Inventor's signature X Michael Butsch

Date September 25, 2001 Country of Citizenship Germany

Residence 32b, Waldweg, D-88718 Daisendorf, Germany (DEX)

Post Office Address same

Full name of second joint inventor, if any

Rainer Baumgart  
(GIVEN NAME) (MIDDLE INITIAL OR NAME) (FAMILY (OR LAST NAME))

Inventor's signature X Rainer Baumgart

Date September 25, 2001 Country of Citizenship Germany

Residence 26, Schleggstrasse, D-81479 Munchen, Germany (DEX)

Post Office Address same

Full name of third joint inventor, if any

(GIVEN NAME) (MIDDLE INITIAL OR NAME) (FAMILY (OR LAST NAME))

Inventor's signature

Date Country of Citizenship

Residence

Post Office Address

(Declaration and Power of Attorney [1-1]—page 6 of 7)

FOR EASY ST 206860

(check proper box(es) for any of the following added page(s)  
that form a part of this declaration)

- ☐ **Signature** for fourth and subsequent joint inventors. *Number of pages added* \_\_\_\_\_  
\* \* \*
- ☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* \_\_\_\_\_  
\* \* \*
- ☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* \_\_\_\_\_  
\* \* \*
- ☐ **Added page for signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)  
\* \* \*
- ☐ **Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.**  
☐ *Number of pages added* \_\_\_\_\_  
\* \* \*
- ☐ **Authorization of practitioner(s) to accept and follow instructions from representative.**  
\* \* \*

(if no further pages form a part of this Declaration,  
then end this Declaration with this page and check the following item)

☒ This declaration ends with this page.

09890745 123104  
TOTAL 57406860